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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/584,141	06/26/2006	Yoshihiro Takayanagi	292509US0PCT	5661
22850	7590	03/17/2009		
OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			EXAMINER HAVLIN, ROBERT H	
			ART UNIT	PAPER NUMBER
			1626	
			NOTIFICATION DATE	DELIVERY MODE
			03/17/2009	ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@oblon.com  
oblonpat@oblon.com  
jgardner@oblon.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/584,141	<b>Applicant(s)</b> TAKAYANAGI ET AL.	
	<b>Examiner</b> ROBERT HAVLIN	<b>Art Unit</b> 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 15 December 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 6-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>See Continuation Sheet</u> .                                  | 6) <input type="checkbox"/> Other: _____                          |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :6/26/06, 8/18/06, 9/1/06, 12/4/08.

### **DETAILED ACTION**

**Status of the claims:** Claims 1-24 are currently pending.

**Priority:** This application is a 371 of PCT/JP04/19581 (12/27/2004), and claims foreign priority to JAPAN 2003-431686 (12/26/2003).

**IDS:** The IDS dated 6/26/06, 8/18/06, 9/1/06, 12/4/08 were considered.

### ***Election/Restrictions***

Applicant's election without traverse of Group I (claims 1-5) in the reply filed on 12/15/08 is acknowledged. Applicant also elected the species of example 4 on page 64 of the specification pertaining to the synthesis of 4-((4S)-Hydroxy-(2S)-pyrrolidinylmethoxy)benzoic acid ethyl ester-1-carboxylic acid benzyl ester.

The following rejection of the generic claim demonstrate that the claims are presently unpatentable. Therefore, the provisional election of species is placed in effect and the claims restricted to the elected species only and the remaining subject matter held withdrawn. Claims 6-24 are hereby withdrawn.

### ***Double Patenting***

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-5 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 7345179. The claims are for a related method having similar reaction conditions that are arranged differently. The starting material in the '179 patent is the compound (c) of the instant application and the subsequent transformations substantially overlap in scope.

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

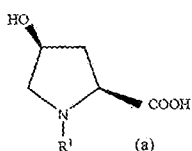
4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,707,987 ('987) in view of EP 0449191 A1 ('191) and March's Advanced Organic Chemistry, 5<sup>th</sup> ed., (2001) ("March").

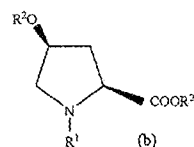
The instant claims read on method of making a compound comprising the steps:

Starting with a compound of the formula:

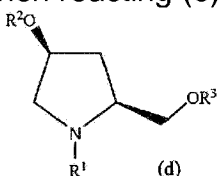
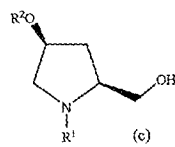


(a), reacting it with an alkyl halide

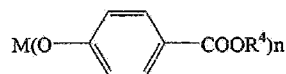
in the presence of a base to produce the compound:



reducing compound (b) to make compound (c):  
then reacting (c) with an aryl/alkyl-sulfonyl halide to make (d):

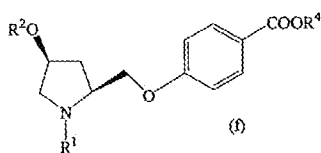


then reacting (d) with (e)



to make (f):

[F'6]

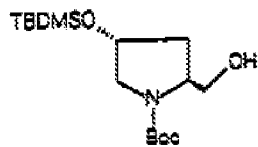


1. *Determining the scope and contents of the prior art.*

EP 0449191 A1 teaches on page 109-110 the starting material of L-hydroxyproline methyl ester hydrochloride, protecting it at the N-position with Boc. The

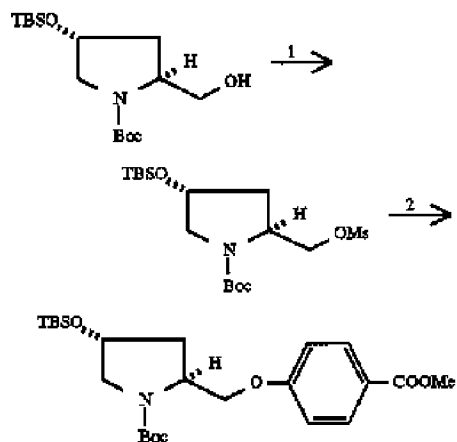
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product was then reacted with TBDMS-chloride, followed by reduction of the ether group to produce:



US 5,707,987 col. 133 methods of making closely related compounds and specifically teaches in reference example 100:

Reference Example 100



March teaches related methods of modifying and protecting the desired groups in a larger synthetic scheme. In addition, the reference teaches the use of various leaving groups such as arylsulfonyl halides (tosyl).

2. *Ascertaining the differences between the prior art and the claims at issue.*

The difference between the prior art and the claims is the particular selection of protecting groups.

3. *Resolving the level of ordinary skill in the pertinent art.*

One of ordinary skill in the art of organic synthesis would be well versed in the teachings of references such as March. One of ordinary skill in the art would consider routine and well within their technical grasp the process of altering protecting groups and optimizing reaction conditions to maximize yield and stereoselectivity. In addition, those of ordinary skill in the art would first look to known synthetic methods in the art that share structural elements with the object of their endeavor.

4. *Considering objective evidence present in the application indicating obviousness or nonobviousness.*

One of ordinary skill in the art would be motivated to optimize yield and stereoselectivity. Based on the teachings of March, '987, and '191, one of ordinary skill in the art would be know how to utilize different protecting groups such as Me instead of TBS. Those of ordinary skill routinely use the a variety of protecting groups such as TBS and Me that are well within their technical grasp and are commonly interchanged in order to routinely optimize the reaction conditions to maximize yield, etc.

The Supreme Court stated in *KSR* "if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond that person's skill." *KSR Intern. Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1731 (2007).

Because varying protecting groups is routinely employed in improving methods of making organic compounds similar to those claimed here, the application of the same technique is obvious. Therefore, **the claims are rejected.**



***Claim Objections***

Claims 4 and 5 are objected to for being in an improper multiply dependent form. See MPEP 608.01(n).

***Conclusion***

The claims are not in condition for allowance.

***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Havlin whose telephone number is (571) 272-9066. The examiner can normally be reached on Mon. - Fri., 7:30am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful the examiner's supervisor, Joe McKane can be reached at (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert Havlin/

/Rebecca L Anderson/

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Primary Examiner, Art Unit 1626